HFI-35

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Cincinnati District Office
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
FAX: (513) 679-2772

WARNING LETTER

Cin WL 5354-0
November 22, 2000

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Suzanne Orcholski, R.T. (R)(M)
Radiology Supervisor
Bryan Medical Group, Inc.
442 West High St.
Bryan, OH 43506

Facility I.D.#: 170506

Dear Ms. Orcholski:

A representative from the State of Ohio acting on behalf of the Food and Drug Administration (FDA) inspected your facility on November 14, 2000. This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States federal law, the Mammography Quality Standards Act (MQSA) of 1992, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following **repeat** Level 2 finding at your facility:

Quality Assurance – Equipment - 21 CFR 900.12(e)(2)(i)-(iv)

Your records revealed that your facility phantom quality control records for the mammography unit were missing for three weeks. The MQSA regulation requires the mammography unit be evaluated by performing at least weekly the image quality evaluation test. The inspection found that your facility failed to perform this quality control test during the weeks of February 7-11; 21-25 and March 13-17, 2000.

The specific problem noted above appeared on your MQSA Facility Inspection Report, which your facility received at the close of the inspection. The problem is identified as **repeat** Level 2 because it identifies a failure to meet a significant MQSA requirement and indicates failure by your facility to implement permanent correction of the problem found during your previous inspection.

Because the condition may be symptomatic of serious underlying problem that could compromise the quality of mammography at your facility, it represents a violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA standards, suspension or revocation of

your facility's FDA certificate, or obtaining a court injunction against performing further mammography.

The other item listed in your November 14, 2000 inspection report identified, as Level 3 should also be corrected. We will verify correction on this item during our next inspection. You are not required to address the Level 3 item in your written response.

It is necessary for you to act on this matter immediately. Please explain the following elements to this office in writing within fifteen (15) working days from the date you received this letter:

- The specific steps you have taken to correct the violation noted in this letter; and
- Each step your facility is taking **to prevent the recurrence** of similar violations.

Please submit sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted).

Please submit your response to:

Mr. R. Terry Bolen
MQSA Compliance Officer
Food & Drug Administration
6751 Steger Drive
Cincinnati, OH 45237-3097
FAX: 513-679-2772

Also, please send a copy to the State radiation control office:

Ms. Cindy Grant
Ohio Department of Health
1 Government Square
Suite 1320
Toledo, OH 43604

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at through the Internet at http://www.fda.gov/cdrh/mammography.

If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact R. Terry Bolen at 513-679-2700, extension 138

Sincerely yours,

Henry L. Fielden
District Director
Cincinnati District Office

c.
OH/CGrant

Priscilla F. Butler, M.S.
Director, Breast Imaging Accreditation Program
American College of Radiology
1891 Preston White Dr.
Reston, VA 20191